

## Extending our leadership in oncology

### **Dr. Andreas Abt**

*Commercial Director/ Deputy Head Roche Pharma Oncology  
LODH Swiss Equities Conference, London, May 3 2006*



This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

- 1 pricing and product initiatives of competitors;
- 2 legislative and regulatory developments and economic conditions;
- 3 delay or inability in obtaining regulatory approvals or bringing products to market;
- 4 fluctuations in currency exchange rates and general financial market conditions;
- 5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
- 6 increased government pricing pressures;
- 7 interruptions in production
- 8 loss of or inability to obtain adequate protection for intellectual property rights;
- 9 litigation;
- 10 loss of key executives or other employees; and
- 11 adverse publicity and news coverage.

Any statements regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share for this year or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

For marketed products discussed in this presentation, please see full prescribing information on our website - [www.roche.com](http://www.roche.com)

All mentioned trademarks are legally protected

---

## Roche in oncology

---

### Growth drivers – our brands

#### Summary

## Q1 '06: A strong start for the year

- Group sales rose 15 % in local currencies, 22 % in CHF
- Oncology strong growth contribution (+52 %<sup>1</sup>)
- Top ten products growing +38 %<sup>1</sup>, top 20 +28 %<sup>1</sup>
- Rituxan approved in US for first rheumatoid arthritis indication
- First in a series of filings in oncology
  - Herceptin for adjuvant breast cancer in US and EU
  - Japanese filings for Avastin in mCRC, Tarceva in NSCLC

## Pharma strongly out-growing worldwide markets

*CHF 1.6 bn additional organic sales*



Sales CHF m	Q1 '05	Q1 '06	% change in	
			local	CHF
Roche Pharma	3,859	4,821	19	25
Genentech	1,341	2,056	40	53
Chugai	955	862	-8	-10
<b>Pharmaceuticals</b>	<b>6,155</b>	<b>7,739</b>	<b>19</b>	<b>26</b>

	% of pharma sales	growth (local)	market growth
Oncology	46 %	52 %	19 % <sup>2</sup>
Transplantation	7 %	14 %	8 % <sup>2</sup>
Virology	7 % <sup>1</sup> /15 %	-3 % <sup>1</sup> /14 %	9 % <sup>1,2</sup>
Renal Anemia	5 %	0 %	9 % <sup>3</sup>
<b>Total</b>	<b>74 %</b>	<b>33 %</b>	

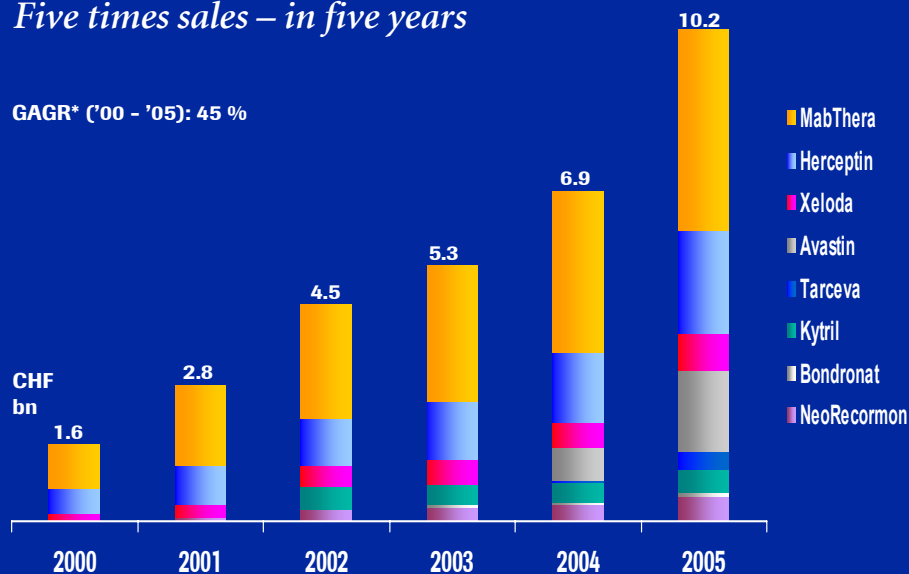
5

## Roche Oncology: clear market leader

*Five times sales – in five years*



GAGR\* ('00 - '05): 45 %



\* Compound Annual Growth Rate

6

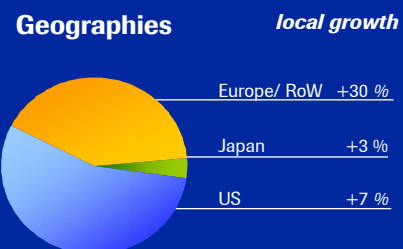
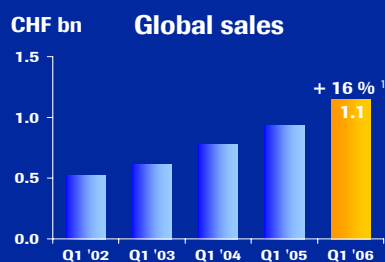
## Roche in oncology

### Growth drivers – our brands

#### Summary

## MabThera / Rituxan

*Increasing penetration in EU/ RoW fuelling growth*



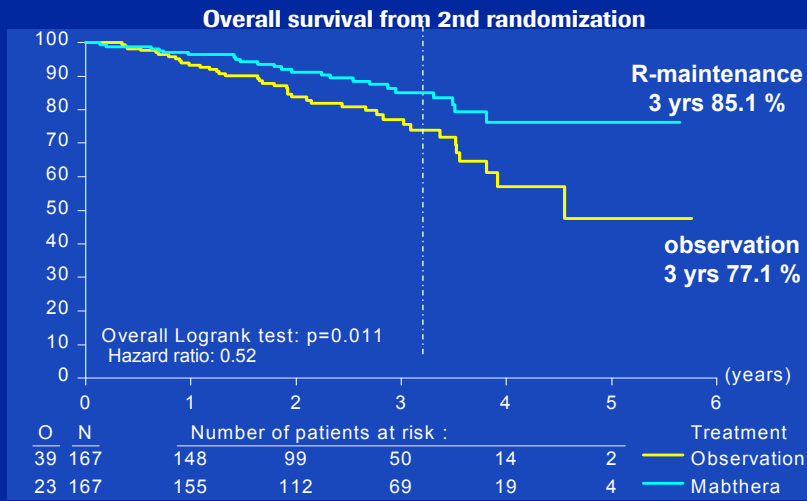
- Sales of CHF 1.1 bn
- Now approved for first-line aNHL treatment in the US
  - filed for first-line iNHL with the FDA in March
- iNHL maintenance approval pending in EU

<sup>1</sup> local growth

# Intergroup phase III trial (EORTC 20981)



## MabThera maintenance in relapsed iNHL



Presented at ASH '05

9

# MabThera



## Three approaches to drive sales

1. increase penetration
2. multiple treatments (re-treatment)
3. prolong treatment (maintenance)

	1 <sup>st</sup> line	Relapse	Maintenance
Indolent NHL	EU: approved '04 US: filed Mar '06 <b>(8 infusions)</b>	EU: approved '98 US: approved '97 <b>(4 infusions)</b>	EU: filed Q4 '05 <b>(8-16 infusions)</b>
Aggressive NHL	EU: approved '02 J: approved '03 US: approved '06 <b>(8 infusions)</b>		
CLL	Phase III	Phase III	

10

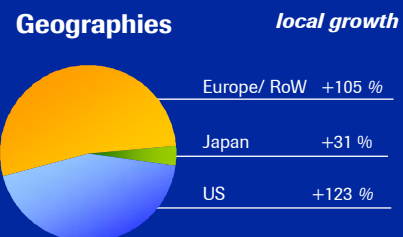
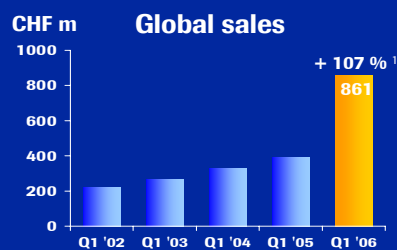
## MabThera

### Summary and outlook

- Outstanding clinical data and extensive development and post-marketing program:
  - 10,000 patients in randomized clinical trials
  - CLL phase III ongoing
- Still significant sales potential – regional upsides:
  - US: CLL and maintenance
  - EU: indolent NHL (1st line and relapse), maintenance and CLL
  - RoW: indolent and aggressive NHL, maintenance and CLL
- Long patent protection
- Limited competition

## Herceptin

### Sales doubled



- Sales of CHF 861 m
- Use in adjuvant BC continues to accelerate growth
- Filed for adjuvant BC in EU and US in Q1 as planned
- TAnDEM data expected in 2006

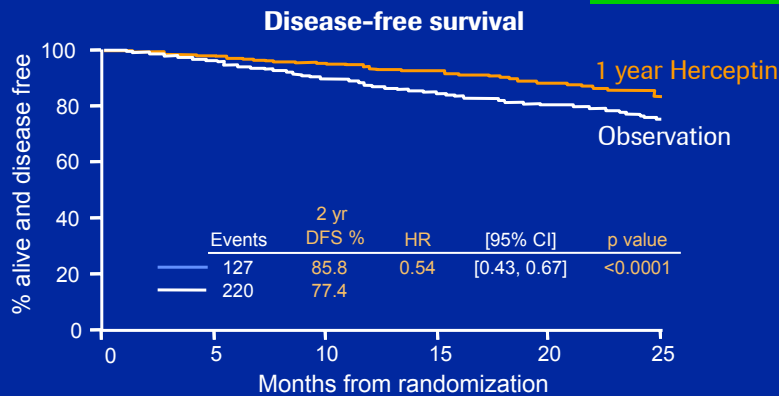
<sup>1</sup> local growth

# Herceptin for adjuvant therapy of BC - HERA



Compelling benefit of 50 % reduction in the risk of disease recurrence

Filed EU & US Q1 '06  
CHMP +ve opinion Apr 28



No. patients at risk :						
1 year Herceptin	1694	1472	1067	629	303	102
Observation	1693	1428	994	580	280	87

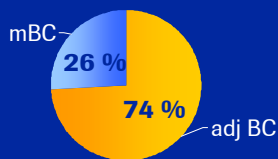
13

## Patients over-expressing HER2 should receive Herceptin: Proven survival benefit

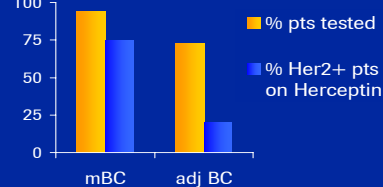


### 5 key EU countries

#### Breast cancer cases



#### % patients tested and treated survey data Q4 '05



- Huge potential in adjuvant BC
  - 4 large randomised studies
  - HERA 2 year data: final analysis '08
- Further up-side in mBC 1st line setting
  - increased penetration
  - combination with hormones

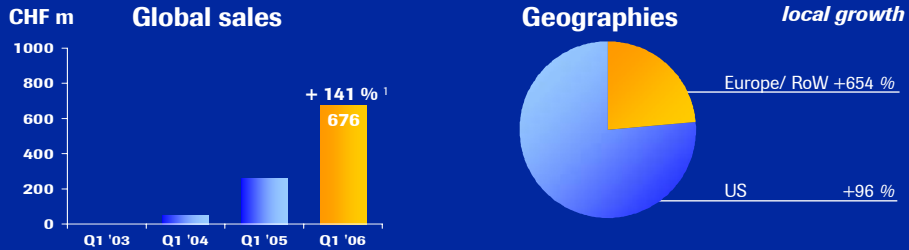
**Herceptin will become the standard of care for HER2 positive breast cancer patients**

14

# Avastin



## Sales more than doubled – strong EU entry



- Sales of CHF 676 m
- Filed for first-line treatment of NSCLC in the US
- Filed for metastatic colorectal cancer in Japan
- Filings currently under preparation: mBC US/EU, mNSCLC in EU, mCRC oxaliplatin/ Xeloda-combo EU
- Update on safety data review for AVANT (adj CC) in May
- First-line RCC phase III data expected this year

<sup>1</sup> local growth

# Avastin: Investment approach paying off



## Proven benefit in 3 tumor types

Indication	Status
<b>mCRC</b> 1 <sup>st</sup> line	<ul style="list-style-type: none"> <li>• <b>35 %</b> reduction in the risk of death</li> <li>• Trial ongoing with oxaliplatin (NO16966)</li> <li>• <b>Approved US/ EU</b></li> </ul>
2 <sup>nd</sup> line	<ul style="list-style-type: none"> <li>• <b>24 %</b> reduction in the risk of death (E3200)</li> <li>• <b>Filed US</b></li> </ul>
<b>mBC</b> 1 <sup>st</sup> line	<ul style="list-style-type: none"> <li>• <b>50 %</b> reduction in the risk of cancer progression (E2100)</li> <li>• <b>33 %</b> reduction in the risk of death<sup>1</sup> (OS)</li> <li>• <b>Filing Q2 '06</b></li> </ul>
<b>NSCLC</b> 1 <sup>st</sup> line	<ul style="list-style-type: none"> <li>• <b>23 %</b> percent reduction in the risk of death (E4599)</li> <li>• AVAIL (BO17704) ongoing with cisplatin/gemcitabine</li> <li>• <b>Filed US Q1 '06, Filing EU 2006</b></li> </ul>

<sup>1</sup> data as presented at ASCO 2005



## Avastin: Establish as “backbone therapy” A combination partner to current standards

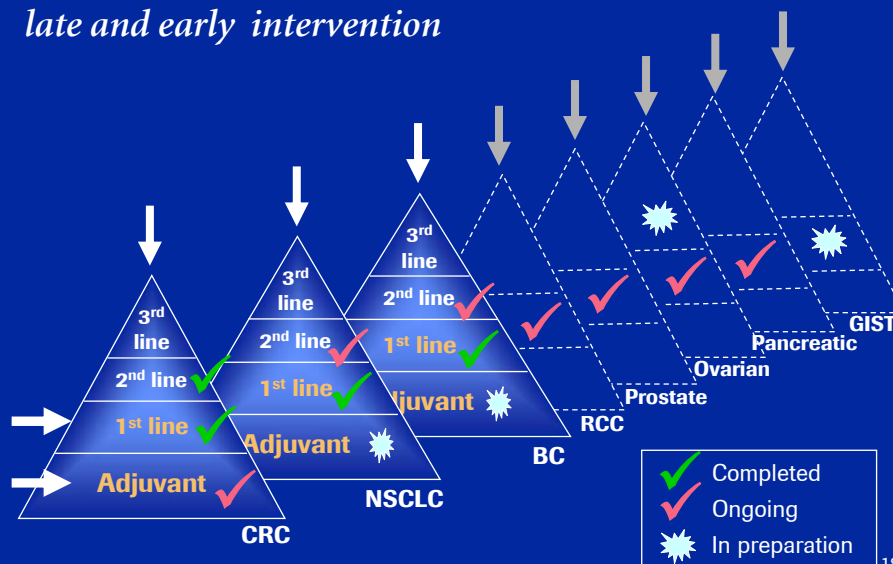


CRC	NSCLC	BC
<ul style="list-style-type: none"> <li>• 5-FU/Leucovorin</li> <li>• Irinotecan</li> <li>❖ Oxaliplatin</li> <li>❖ Xeloda</li> <li>○ New biologics</li> </ul>	<ul style="list-style-type: none"> <li>• Platinum-based chemotherapy</li> <li>❖ Single agent (navelbine or gemcitabine)</li> <li>❖ Non-platinum based regimens</li> <li>❖ Tarceva</li> <li>○ New biologics</li> </ul>	<ul style="list-style-type: none"> <li>• Taxanes</li> <li>❖ Anthracyclines</li> <li>❖ Xeloda</li> <li>○ Hormones</li> <li>○ Herceptin</li> <li>○ New biologics</li> </ul>

- positive data
- ❖ trials ongoing
- trials planned

17

## Avastin: A unique development approach Parallel development: all main cancer types, late and early intervention



18



## Trials of Avastin and Oxaliplatin

*Expanding usage in first-line therapy for mCRC*

Trial	n	Treatment	Status
NO16966	1,920	FOLFOX-4 ± Avastin vs. XELOX ± Avastin	Recruitment completed, final data and EU filing '06
TREE-2	223	FOLFOX-6 + Avastin vs. FOL + Avastin vs XELOX + Avastin	Final data to be presented at ASCO '06

FOLFOX = infused 5-FU/LV + oxaliplatin  
 XELOX = Xeloda + oxaliplatin  
 bFOL = bolus 5-FU + oxaliplatin

19



## Trials in adjuvant colon cancer

*Moving into early treatment*

Phase III Trials	n	Treatment	Status
<b>AVANT</b>	3,450	FOLFOX-4 ± Avastin vs. XELOX + Avastin	Started Q4 '04, filing post 2009
<b>NSABP C-08</b>	2,500	FOLFOX-6 ± Avastin	Started Q3 '04

- Recruitment in AVANT temporarily stopped
- DSMB analysis and further update will be provided in May

20



## Further phase III trials in NSCLC & BC

*Covering key stages and combinations*

NSCLC	Treatment	Status
adjuvant	TBD	In preparation
1st line non-squamous AVAIL (E4599)	Cisplatin/Gemcitabine ± Avastin	Filed in US, Ongoing in EU
1st line maintenance ATLAS	CT + Avastin → Avastin ± Tarceva	Initiated Q1 '05
2nd line	Tarceva ± Avastin	Ongoing

BC	Treatment	Status
1st line mBC RIBBON-1	CT (inc. Xeloda) ± Avastin	Initiated Q4 '05
2nd line mBC RIBBON-2	CT ± Avastin	Initiated Q1 '06

21



## Trials expanding the portfolio even further

*A molecule with multi-tumor therapy potential*

Phase III Trials	n	Treatment	Status
<b>RCC</b>			
1st line			
CALGB90206	700	Interferon ± Avastin	Data in '06
AVOREN	638	Interferon ± Avastin	Data in '06; Filing EU '07
<b>Pancreatic Ca</b>			
1st line			
CALGB80303	540	Gemcitabine ± Avastin	Ongoing
BO17706	600	Gemcitabine/Tarceva ± Avastin	Ongoing, Filing EU '08
<b>Prostate Ca</b> refractory	1,000	Taxotere ± Avastin	Started Q2 '05, Filing EU post '09
<b>Ovarian Ca</b>			
1st line			
GOG 218	2,000	Carboplatin/ paclitaxel ± Avastin	Started Q3 '05
ICON7	1,000	Carboplatin/ paclitaxel ± Avastin	In preparation, Filing EU post '09

22

## Avastin



### *Proven survival benefit in multiple tumour types*

- Strongest launch of an oncology product
  - sales 1.7 bn CHF in 2005 in less than 2 years on the market
- Extensive development program unique in breadth and scope
  - ongoing projects in 8 tumour types, in different settings
  - over 20,000 patients (excluding collaborative trials)
- Establishing standards of care

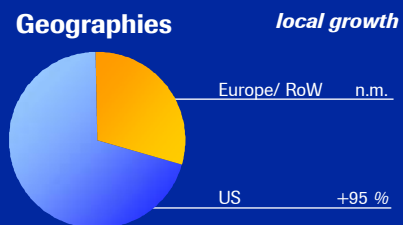
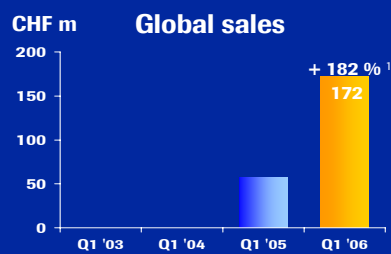
**Avastin-based treatment regimens on track to become backbone therapy for all solid tumors**

23

## Tarceva



### *Strong launch in Europe*



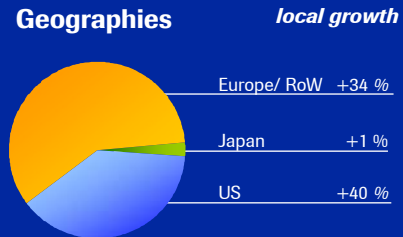
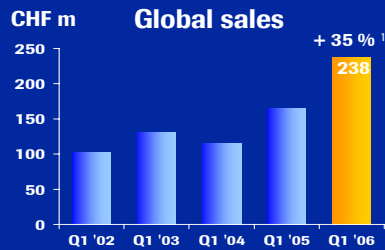
- Sales of CHF 172 m
- Very successful initial roll-out in Europe
- Pancreatic cancer under regulatory review in EU
- Filed for advanced NSCLC in Japan

<sup>1</sup> local growth

24

## Xeloda

*Increasing use in adjuvant colon cancer*



- Sales of CHF 238 m
- Successful launch in adjuvant colon cancer (monotherapy)
  - US market share in adjuvant colon cancer around 20 %<sup>2</sup>
- Positive phase III data in gastric cancer, full data at ASCO
- Filing of 1st line mCRC combo & gastric cancer on track for this year

<sup>1</sup> local growth

<sup>2</sup> MAT March 2006

## Roche in oncology

### Growth drivers – our brands

### Summary

## Data to be presented at upcoming ASCO

*Reinforcing our oncology leadership*



Product	Indication	Trial	Regimen	Phase	Data
Avastin	mCRC 1st line	BRITE	Avastin + standard CRC chemotherapy	IV	Safety and early efficacy data
Avastin	mCRC 1st line	TREE1, TREE2	XELOX vs bFOL vs FOLFOX (+ Avastin in all arms of TREE2)	II	Final
Avastin	mCRC 1st line	BEAT	Avastin + standard CRC chemotherapy	III/IV	Safety and early efficacy data
Avastin + Tarceva	NSCLC 2nd line	OSI2950	Taxotere or Alimta vs. Taxotere or Alimta + Avastin vs. Avastin + Tarceva	II	Final
Herceptin	mBC 1st line	BCIRG 007	Taxotere + Herceptin vs. Taxotere + Carboplatin + Herceptin	III	Interim (TTP)
Xeloda	Gastric Ca 1st line	ML17032	Cisplatin + Xeloda vs. Cisplatin + 5FU	III	Final
MabThera	iNHL	FL2000	CTx12 vs. CTx6 + MabThera	III	Final
Diagnostics microarray	Leukemia	MILE	molecular sub-classification of leukemia by gene expression profiling vs. standard lab methods	Validation	Interim data (stage I)

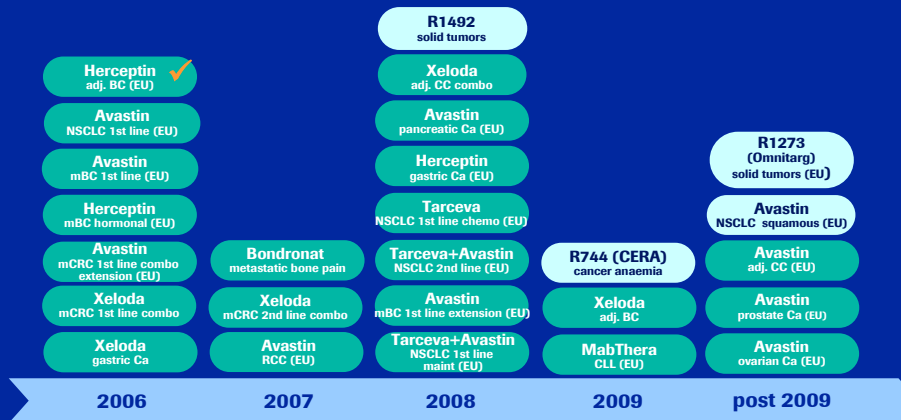
Roche Oncology Event: Zurich, June 19

27

## Major Roche managed projected submissions in Oncology over the next years



Phase II  
Phase III



Status as of March 31, 2006

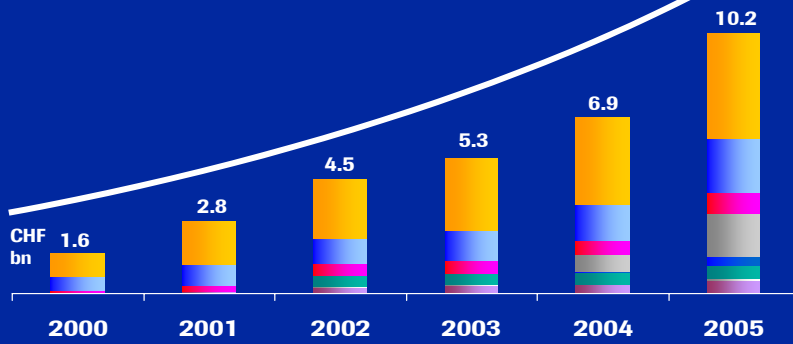
Unless stated otherwise, submissions will occur in US and EU

28

**Growing from an already strong position ...**  
*...and setting new standards in Oncology care*



- Huge growth potential in commercialised products
- Extensive development program
- Well positioned ahead of competition



29

